



1F12 1647

PATENT  
Attorney Docket No. MERCK-2056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Hartmann *et al.* CONF. NO.: 2626  
SERIAL NO.: 09/708,506 GROUP NO.: 1647  
FILING DATE: November 9, 2000 EXAMINER: DeBerry, Regina M.  
TITLE: Erythropoietin Forms with Improved Properties

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**

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- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

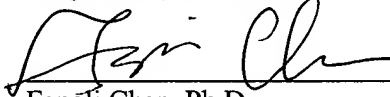
Applicants believe no additional fee is due for consideration of this submission. Nevertheless, if such a fee is required, please debit account 20-0531.

Date: September 17, 2004  
Reg. No. 51,551

Tel. No.: (617) 310-8389  
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3113120\_1

Respectfully submitted,



Fangli Chen, Ph.D.  
Agent for Applicants  
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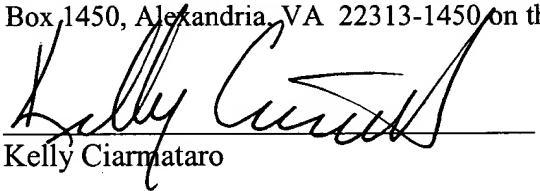
PATENT  
Attorney Docket No. MERCK-2056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Hartmann *et al.*  
SERIAL NO.: 09/708,506 GROUP NO.: 1647  
FILING DATE: November 9, 2000 EXAMINER: DeBerry, Regina M.  
TITLE: ERYTHROPOIETIN FORMS WITH IMPROVED PROPERTIES

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in a box addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the 17<sup>th</sup> day of September, 2004.

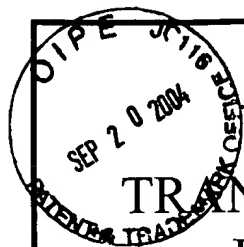
  
Kelly Ciarmataro

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

1. Transmittal Form (1 page);
2. Fee Transmittal Form (1 page);
3. Supplemental Information Disclosure Statement (2 pages);
4. Form PTO-1449 (3 pages);
5. Copies of cited references A97-A113, B107 and C245-C264;
6. A check in the amount of \$180.00; and
7. A return receipt postcard.



# TRANSMITTAL FORM

Application Serial Number	09/708,506
Filing Date	November 9, 2000
First Named Inventor	Hartmann <i>et al.</i>
Group Art Unit	1647
Examiner Name	DeBerry, Regina M.
Attorney Docket No.	MERCK-2056
Patent No.	Not applicable
Issue Date	Not applicable

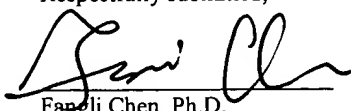
## ENCLOSURES (check all that apply)

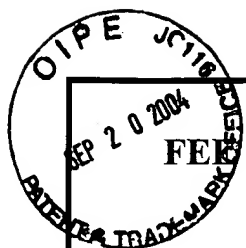
<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences
<input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]	<input type="checkbox"/> Formal Drawing(s)	<input type="checkbox"/> Appeal Brief (in triplicate)
<input type="checkbox"/> Petition for Extension of Time	<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal	<input type="checkbox"/> Status Inquiry
<input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations (A97-A113, B107 and C245-C264)	<input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)	<input checked="" type="checkbox"/> Return Receipt Postcard
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Certificate of First Class Mailing
<input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application	<input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8
	<input type="checkbox"/> Small Entity Statement	<input type="checkbox"/> Additional Enclosure(s) (please identify below)
	<input type="checkbox"/> CD(s) for large table or computer program	
	<input type="checkbox"/> Amendment After Allowance	
	<input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	

## CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator  
Testa, Hurwitz & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110  
Tel. No.: (617) 248-7000  
Fax No.: (617) 248-7100

## SIGNATURE BLOCK

Respectfully submitted,  
  
Date: September 17, 2004  
Reg. No. 51,551  
Tel. No.: (617) 310-8389  
Fax No.: (617) 248-7100  
Fangli Chen, Ph.D.  
Agent for Applicants  
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High Street Tower  
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Boston, MA 02110



**FEE TRANSMITTAL**  
**FY 2004**

*Complete if Known*

Application Serial Number	09/708,506
Filing Date	November 9, 2000
First Named Inventor	Hartmann <i>et al.</i>
Group Art Unit	1647
Examiner Name	DeBerry, Regina M.
Attorney Docket No.	MERCK-2056

**METHOD OF PAYMENT**

1. ☒ Payment Enclosed:  
☒ Check ☐ Money Order ☐ Other
2. ☒ The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 20-0531.  
☐ Required Fees (copy of this sheet enclosed).  
☒ Additional fee required under 37 CFR 1.16 and 1.17.  
☒ Overpayment Credit.
3. ☐ Applicant claims small entity status.

**FEE CALCULATION**

**1. FILING FEE**

**Large Entity**

Fee (\$)	Fee Description	Fee Paid
770	Utility filing fee	
340	Design filing fee	
160	Provisional filing fee	

Number Filed	Number Extra	Rate	Amount
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Total Claims - 20 = x \$ 18.00 =

Independent Claims - 3 = x \$ 86.00 =

☐ Multiple Dependent Claim(s), if any \$290.00 =

TOTAL:

SMALL ENTITY DISCOUNT:

**SUBTOTAL (1)** (\$ ) 0.00

**2. AMENDMENT CLAIM FEES**

Claims Remaining After Amend.	Highest No. Previously Paid For	Present Extra	Rate	Fee Paid
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Total - = x \$ 18.00 =

Indep. - = x \$ 86.00 =

☐ First Presentation of Multiple Dep. Claim + \$290.00 =

TOTAL: (\$ )

SMALL ENTITY DISCOUNT: (\$ )

**SUBTOTAL (2)** (\$ ) 0.00

**FEE CALCULATION (continued)**

**3. ADDITIONAL FEES**

Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid
130	65	Surcharge - late filing fee or oath	
50	25	Surcharge - late provisional filing fee or cover sheet	
130	130	Non-English specification	
2,520	2,520	Request for ex parte reexamination	
110	55	Extension for reply within first month	
420	210	Extension for reply within second month	
950	475	Extension for reply within third month	
1480	740	Extension for reply within fourth month	
2010	1005	Extension for reply within fifth month	
330	165	Notice of Appeal	
330	165	Filing a brief in support of an appeal	
290	145	Request for oral hearing	
130	130	Petitions to the Commissioner	
180	180	Submission of Information Disclosure Statement	180.00
770	385	Filing a submission after final rejection (37 CFR 1.129(a))	
770	385	For each additional invention to be examined (37 CFR 1.129(b))	
100	100	Certificate of Correction for applicant's error	
110	55	Submission of Terminal Disclaimer	
Other fee (Specify)			
Other fee (Specify)			

**SUBTOTAL (3)** (\$ ) 180.00

SUBTOTAL (1) 0.00

SUBTOTAL (2) 0.00

SUBTOTAL (3) 180.00

**TOTAL** (\$ ) 180.00

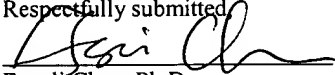
**CORRESPONDENCE ADDRESS**

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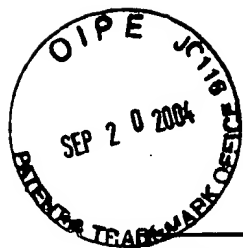
Patent Administrator  
Testa, Hurwitz & Thibault, LLP  
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**SIGNATURE BLOCK**

Respectfully submitted,

  
Fangli Chen, Ph.D.  
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Boston, MA 02110

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FORM PTO - 1449

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MERCK-2056

APPLICANT(S): Hartmann *et al.*

SERIAL NO.: 09/708,506

FILING DATE: 11/9/00

GROUP: 1647

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A97	5,601,819	2/11/97	Wong et al.			
	A98	5,891,680	4/6/99	Lieschke et al.			
	A99	5,994,104	11/30/99	Anderson et al.			
	A100	6,429,199	8/6/02	Krieg et al.			
	A101	6,500,641	12/31/02	Chen et al.			
	A102	6,551,592	4/22/03	Lindhofer et al.			
	A103	6,646,113	11/11/03	Dreyfuss et al.			
	A104	2002/0037558	3/28/02	Lo et al.			
	A105	2002/0146388	10/10/02	Gillies			
	A106	2003/0139365	7/24/03	Lo et al.			
	A107	2003/0139575	7/24/03	Gillies			
	A108	2004/0013640	1/22/04	Zardi et al.			
	A109	2004/0033210	2/19/04	Gillies			
	A110	2004/0043457	3/4/04	Schumacher et al.			
	A111	2004/0053366	3/18/04	Lo et al.			
	A112	2004/0072299	4/15/04	Gillies et al.			
	A113	2004/0082039	4/29/04	Gillies et al.			

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B107	WO 93/20185	10/14/93	PCT					

EXAM. INIT. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

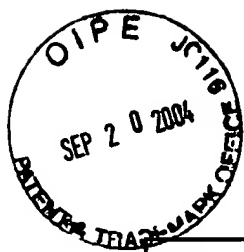
	C245	Chapman et al., (1994), "Mapping Effector Functions of a Monoclonal Antibody to GD3 by Characterization of a Mouse-Human Chimeric Antibody," <i>Cancer Immuno. Immunother.</i> , 39:198-204.
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EXAMINER

DATE CONSIDERED



FORM PTO - 1449		ATTORNEY DOCKET NO.: MERCK-2056
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Hartmann <i>et al.</i>
		SERIAL NO.: 09/708,506
		FILING DATE: 11/9/00      GROUP: 1647
C246	Cruse et al., (eds.), (1995), <u>Illustrated Dictionary of Immunology</u> , p.158, CRC Press, NY.	
C247	De la Salle et al., (1996), "FcγR on Human Dendritic Cells," in <u>Human IgG Receptors</u> , pp. 39-55, van de Winkel et al. (eds.), R.G. Landes Co.	
C248	Dorai et al., (1991), "Aglycosylated Chimeric Mouse/Human IgG1 Antibody Retains Some Effector Function," <u>Hybridoma</u> , 10(2):211-217.	
C249	Dorai et al., (1992), "Role of Inter-Heavy and Light Chain Disulfide Bonds in the Effector Functions of Human IgG1," <u>Molecular Immunology</u> , 29(12):1487-1491.	
C250	Elliott et al., (1996), "Fine-Structure Epitope Mapping of Antierythropoietin Monoclonal Antibodies Reveals a Model of Recombinant Human Erythropoietin Structure," <u>Blood</u> , 87(7):2702-2713.	
C251	Gillies et al., (1991), "Targeting Human Cytotoxic T Lymphocytes to Kill Heterologous Epidermal Growth Factor Receptor-Bearing Tumor Cells: Tumor-Infiltrating Lymphocyte/Hormone Receptor/Recombinant Antibody," <u>J. Immunology</u> , 146(3):1067-1071.	
C252	Handgretinger et al., (1995), "A Phase I Study of Human/Mouse Chimeric Anti-ganglioside GD2 Antibody ch14.18 in Patients with Neuroblastoma," <u>European J. Cancer</u> , 31A(2):261-267.	
C253	Hurn et al., (1980), "Production of Reagent Antibodies," <u>Methods in Enzymology</u> , 70: 104-142.	
C254	Isenman et al., (1975), "The Structure and Function of Immunoglobulin Domains: II. The Importance of Interchain Disulfide Bonds and the Possible Role of Molecular Flexibility in the Interaction between Immunoglobulin G and Complement," <u>J. Immunology</u> , 114(6):1726-1729.	
C255	Lo et al., (1992), "Expression and Secretion of an Assembled Tetrameric CH2-deleted Antibody in <i>E. Coli.</i> ," <u>Hum. Antibod. Hybridomas</u> , 3:123-128.	
C256	Maecker et al., (1997), "DNA Vaccination with Cytokine Fusion Constructs Biases the Immune Response to Ovalbumin," <u>Vaccine</u> , 15(15):1687-1696.	
C257	Mueller et al., (1990), "Enhancement of Antibody-Dependent Cytotoxicity With A Chimeric Anti-GD2 Antibody," <u>J. Immunology</u> , 144(4):1382-1386	
C258	Mueller et al., (1990), "Serum Half-Life and Tumor Localization of a Chimeric Antibody Deleted of the CH2 Domain and Directed Against the Disialoganglioside GD2," <u>Proc. Natl. Acad. Sci. USA.</u> , 87:5702-5705.	
C259	Naramura et al., (1993), "Therapeutic Potential of Chimeric and Murine Anti-(Epidermal Growth Factor Receptor) Antibodies in a Metastasis Model for Human Melanoma," <u>Cancer Immuno. Immunother.</u> , 37:343-349.	
C260	Reisfeld et al., (1994), "Potential of Genetically Engineered Anti-Ganglioside GD2 Antibodies for Cancer Immunotherapy," <u>Prog. Brain Res.</u> , 101:201-212	
C261	Saleh et al., (1992), "Phase I Trial of the Chimeric Anti-GD2 Monoclonal Antibody ch14.18 in Patients With Malignant Melanoma," <u>Hum. Antibod. Hybridomas</u> , 3:19-24.	
EXAMINER		DATE CONSIDERED



<b>FORM PTO - 1449</b>		<b>ATTORNEY DOCKET NO.: MERCK-2056</b>	
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>		<b>APPLICANT(S): Hartmann <i>et al.</i></b>	
		<b>SERIAL NO.: 09/708,506</b>	
		<b>FILING DATE: 11/9/00</b>	<b>GROUP: 1647</b>
	C262	Sallusto et al., (1994), "Efficient Presentation of Soluble Antigen by Cultured Human Dendritic Cells Is Maintained by Granulocyte/Macrophage Colony-stimulating Factor Plus Interleukin 4 and Downregulated by Tumor Necrosis Factor $\alpha$ ," <u>J. Exp. Med.</u> , 179:1109-1118.	
	C263	Schlom (1991), "Monoclonal Antibodies: They're More and Less Than You Think," in <u>Molecular Foundations of Oncology</u> , pp. 95-133.	
	C264	Wen et al., (1994), "Erythropoietin Structure-Function Relationships: Identification of Functionally Important Domains," <u>J. Biological Chemistry</u> , 269(36):22839-22846.	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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